
510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

SEP 25 2002

Siemens Medical Solutions USA, Inc.

Electromedical Systems Group, PCS

Danvers, MA 01923

Tel: (978) 907-7500

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Official Correspondent: Connie Hertel, Director

Quality Assurance & Regulatory Affairs

Contact person for this submission: Penelope H. Greco

Date submission was prepared: August 29, 2002

Trade Name, Common Name and Classification Name:A. Trade Name:

Siemens INFINITY Modular Monitors (SC 7000 / SC 9000XL / SC 8000)

B. Common Name, Classification Name, Class and Regulation Number:

<u>Common Name</u>	<u>Product Code</u>	<u>Class</u>	<u>Regulation Number</u>
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	III	21 CFR 870.1025
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025

Legally Marketed Device Identification:

INFINITY SC 8000 Monitor, 510(k) K983632 / K990563

INFINITY SC 7000 / SC 9000XL Modular Monitors, 510(k) K003243/K982730/ K980882

INFINITY Explorer, 510(k) K013515

MICRO2+, 510(k) K012770

Description of Modification:

The modifications implemented with the release of software version VF2 have not altered the basic fundamental technology of the INFINITY Modular Monitors. Testing with VF2 software indicates no new issues relative to safety and efficacy. The release of software version VF2 includes the following primary modifications:

1. Wireless capability
2. Non-invasive blood pressure with step deflation
3. MICRO₂+ (K012770) interface
4. Support for Masimo sensors

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Wireless Capability

The INFINITY Modular Monitors (SC 7000 / SC 8000 / SC 9000XL) with Wireless Option (a password protected option) allows the monitor to operate in a wireless network configuration. A wireless ethernet adapter installed in the PCMCIA port communicates with the INFINITY Network (K955059) through installed access points hardwired to the network. All patient related and network data is transmitted to the pre-installed access points allowing the transmitted data from the monitor to be viewed at an assigned MultiView WorkStation (K955059). This configuration provides the network with the same functionality as a hardwired system.

NIBP Step Deflation

The Infinity Monitoring System utilizes the oscillometric method to measure noninvasive blood pressure (NIBP). With the SC7000/8000/9000XL VF2 release, the NIBP algorithm has changed from a linear to stepped deflation system.

Second SpO2 - MicroO2+ Interface

The INFINITY Modular Monitor (SC 7000 / SC 8000 / SC 9000XL) VF2 release supports two simultaneous SpO2 measurements. Using a serial port already available on the monitors, the MicroO2+ pulse oximeter (K012770) can communicate with the monitors using a RS232 serial communication and power supply cable connected to the serial port on the monitor. The stand-alone MicroO2+ pulse oximeter transmits SpO2 and Pulse values to the monitor.

Support for Masimo Sensors

The monitor supports the use of Masimo SpO2 sensors via a password protected option and a specific adapter cable. Clinical accuracy studies referenced to co-oximetry (see Section J) were conducted by Masimo using the following sensors in conjunction with the INFINITY Modular monitors:

- LNOP-Adt
- LNOP-Pdt
- LNOP-Neo
- LNOP-NeoPt
- LNOP-DCI
- LNOP-DCIP
- LNOP-YI
- LNOP-Ear
- NR 125

Intended Use:

The INFINITY Modular Monitors are intended for multi-parameter patient monitoring. The devices will produce visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. These devices will connect to a Siemens R50 Bedside recorder, either directly or via the INFINITY Network.

Assessment of non-clinical performance data for equivalence: See Section J

Assessment of clinical performance data for equivalence: See Section J

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Section J



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2002

Siemens Medical Solutions USA, Inc
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K022889

Trade Name: Siemens Medical INFINITY Modular Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: August 29, 2002
Received: August 30, 2002

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

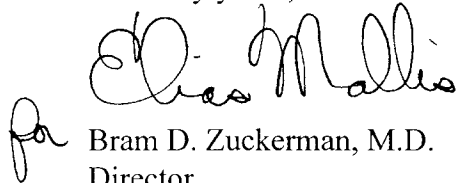
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". To the left of the signature is a small, stylized handwritten mark that looks like "for".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022889Device Name: Siemens INFINITY Modular Monitors (SC 7000 / SC 9000XL / SC 8000)

Indications for Use:

The INFINITY Modular monitors are capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- Apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis
- tcpO2/tcpCO2
- EEG signals
- FiO2

With the MultiGas and MultiGas+ modules the monitors are capable of measuring respiration rate, Inspired and expired Carbon Dioxide (CO₂), inspired and expired Oxygen (MultiGas+ only), average inspired Oxygen (MultiGas only), inspired and expired gas concentrations of Enflurane, Halothane, Isoflurane, Desflurane, Sevoflurane, and Nitrous Oxide.

With etCO₂ the monitors can measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode; and with etCO₂+Respiratory Mechanics, spirometry and carbon dioxide can be monitored.

The monitors can interface with specific third party devices via an MIB protocol converter.

The devices are intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output, ST Segment Analysis, and arrhythmia which are intended for use in the adult and pediatric populations only; etCO₂ sidestream which is not available in neonatal mode; and tcpO₂ which is to be used in the neonatal population only when the patient is not under gas anesthesia.*

MRI Compatibility Statement:

The INFINITY Modular Monitors are not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number 510M0110